

**REMARKS/ARGUMENTS**

Claims 1-18 and 22-29 are currently pending in the present application. Claims have been withdrawn in view of a Restriction Requirement. Claims 19-21 have been canceled without prejudice or disclaimer.

Claims 1-18 and 22-28 have been amended for minor editorial purposes and for compliance with standard U.S. patent practice, and to recite statutory subject matter. Claim 1 has also been amended to include a thickness range recited in claim 9.

These amendments and the new claim are supported by the claims and specification, as originally filed. No new matter has been added.

Reconsideration of the application is respectfully requested in view of the following remarks.

**Rejection under 35 U.S.C. § 102(e)**

The rejection of claims 1-10, 22-23 and 25 under 35 U.S.C. § 102(e) as anticipated by Larsson et al. (U.S. Patent No. 6,689,170) is respectfully traversed.

The reference does not describe or suggest the implant according to the claimed invention.

As the Office is aware, anticipation requires the disclosure, in a reference, of “each and every element” recited in the claims. MPEP § 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). There must be no difference between the claimed invention and reference disclosure for an anticipation rejection under 35 U.S.C. 102. *See Scripps Clinic and Res. Found. v. Genetech, Inc.*, 927 F.2d 1565, 1576, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991).

Turning to amended claim 1, the implant comprises, *inter alia*, titanium and having one or more surfaces which can be applied in or on tissue areas and/or bone growth areas, one or more of the said surfaces being arranged with a depot for bone-growth-initiating or bone-growth-stimulating substance,

wherein the depot is formed by ***a pore arrangement in a relatively thick oxide layer on the titanium, wherein the oxide layer has a thickness in the range of 1 - 20  $\mu$ m***, and

wherein the substance, for a period of time, is acted on by, or works with, one or more release functions which permit an essentially controlled release of substance to the respective surrounding tissue or tissue/bone growth areas.

Applicant notes that the thickness of the oxide layer is also recited in independent claim 22 (an implant).

Larsson et al., on the other hand, generally describes an “implant element” for implantation in bone tissue, developed in view of “comprehensive experimental stud[ies] using differently modified titanium surfaces.” Col. 11, lines 9 - 58, *see also* abstract and claims. However, throughout the several experimental studies described in the reference, including the figures, there is no indication of specifically forming “a pore arrangement in a relatively thick oxide layer on the titanium, wherein the oxide layer has a thickness in the range of 1 - 20  $\mu\text{m}$ .” *See* the Discussion section at cols. 18 - 22, which describes “the relative importance of different surface properties” of the implant.

In fact, contrary to the pore arrangement and thickness of the claimed invention, Larsson et al. explicitly recites that the implants were “surface modified” to achieve an oxide thickness range on a nano-scale, and that such a property is “advantageous” (in comparison to other thickness ranges and other various properties). *Id.* at col. 22, lines 34 - 49. Applicant also directs the Office’s attention to Table 1, cols. 23 - 24 of the reference, which recite nano-scale thickness ranges entirely different than the claimed invention.

Therefore, for at least these reasons, the claimed invention is novel and not anticipated by Larsson et al. Accordingly, withdrawal of the rejection is requested.

#### **Rejection under 35 U.S.C. § 103(a)**

The rejection of claim 24 under 35 U.S.C. § 103(a) as obvious over Larsson et al. is respectfully traversed for the reasons indicated above and the additional reasons below.

Applicant notes the Office’s appreciation of the reference’s failure to describe the highly porous parameter and range recited in claim 24, in which Applicant agrees that the reference is deficient.

Applicant also notes the Office’s assertion that that the parameter and range would be obvious, since it would be considered an optimum or workable range achieve through routine

experimentation and an obvious extension of the prior art. However, Applicant disagrees with the Office's position, since Larsson et al. clearly recites several references and studies, and provides (comparatively) the results of several experiments, in which the parameter and range of claim 24 is clearly not described or shown as advantageous. Further, there is no indication or apparent reason, other than hindsight of the present specification, that one would modify the reference to achieve the claimed invention.

Therefore, the claimed invention is not obvious over Larsson et al. Accordingly, withdrawal of the rejection is requested.

#### **Rejection under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph**

The rejection of claims 1-10 and 22-25 under 35 U.S.C. § 112, second paragraph is traversed and obviated by amendment. As shown above, the claims have been amended to remove language that includes the phrases "consisting of" and "for example", and any other such language that might render the claims indefinite.

Accordingly, the withdrawal of the rejection is requested.

#### **Rejection for Obviousness-Type Double Patenting**

The claims have been rejected on the ground of nonstatutory obviousness-type double patenting, as follows: 1) claims 1-6, 9 and 22 over claims 1-3, 5 and 8 of U.S. Patent No. 7,048,541; 2) claims 1-6, 8-10 and 22-25 over claims 1, 7-9 of co-pending U.S. Application No. 10/482,727; and 3) claims 1-6, 8-10 and 22-25 over claims 4-5, 7 and 10 of co-pending U.S. Application No. 10/482,737. In view of the double patenting rejections, Applicant requests that the Office hold these rejections in abeyance until allowable subject matter is indicated.

#### **Objection to Oath/Declaration**

The Office Action indicates that the as-filed declaration is defective, since the document recites 37 CFR 1.56(a) and not 37 CFR 1.56.

Applicant traverses the Office's objection, since the applicable "duty to disclose" statement is clearly recited in the as-filed declaration, and the recited rule section (1.56(a)) specifically contains the relevant "duty to disclose" definition. In particular, 37 CFR 1.56(a) specifically sets forth the information that the Patent Office considers material to patentability.

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Therefore, the as-filed declaration should be considered compliant, and a new or substitute declaration that merely removes the rule section indicator “(a)” should not be necessary.

Accordingly, withdrawal of the objection is requested.

In the event the Examiner believes an interview might serve in any way to advance the prosecution of this application, the undersigned is available at the telephone number noted below.

The present Amendment/Response is filed concurrently with a fee for a one-month extension of time. However, if any additional fees are due, please charge our Deposit Account No. 22-0185, under Order No. 21547-00286-US from which the undersigned is authorized to draw.

Dated: March 10, 2008

Respectfully submitted,

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